JUL 25 2006

510(k) Summary K061582

The following information is provided following the format of 21 CFR 807.92 for the VariSource 200 HDR Brachytherapy Afterloader.

1. **Submitter:** Varian Medical Systems
   3100 Hansen Way M/S E-110
   Palo Alto, CA 94304-1129
   Contact Name: Vy Tran
   Phone: (650) 424-5731
   Fax: (650) 842-5040
   Email: vy.tran@varian.com
   Date summary was prepared: June 1, 2006

2. **Name of the Device:** **VariSource 200 HDR Afterloader**
   Trade/Proprietary Name: VariSource 200 HDR Afterloader
   Common or Usual Name:
   Classification Name: Radiological Image Processing System
   21 CFR §892.5700
   Class II
   Product Code: 90 JAQ

3. **Predicate Devices** to claim substantial equivalence:
   a. VariSource K(945383)

4. **Description of the Device:** The VariSource 200 Series High Dose Rate Afterloader system is a computer controlled remote electro/mechanical system used for medical purposes, for placing a NiTiNol wire incorporating an irradiated iridium seed internally or close by, a malignant tumor or tumor bed in a practice known as brachytherapy.

   Hardware Platform and Operating System

   The console control application runs on standard Intel PCs under a DOS operating systems. The firmware controlling the High Dose Rate Afterloader runs on an embedded Intel 188 processor.

   Peripherals and Accessories

   The 200 Series control console provides real time information of wire position and system status and interfaces with a printer in order to provide a hard copies of a treatment prescriptions and delivery records. In addition the 200 Series control

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console can receive treatment plans from a treatment planning application (not part of this submission), this information is transferred via a floppy disk.

5. **Intended Use Statement:** The VariSource 200 System is a computer controlled remote HDR Afterloader used to place a high activity radioactive source within a needle(s) or applicator(s) which have previously been placed for a specified clinical purpose in a patient.

The radioactive source (enclosed within the wire/cable) is driven via coupling catheters (Transfer Guide Tubes) from the Afterloader into needles or applicators within or on the patient.

The length of time and position that the High Dose Rate source spends within the needle or applicator is controlled in accordance with an Irradiation Treatment Prescription.

6. **Summary of the Technological Characteristics:** The Substantial Equivalence Comparison Chart provides a comparison of the technological characteristics to those of the predicate devices. This chart is located in Tab 9 of the submission.

HDR Product Comparison Chart

The following table represents information as known to Varian from a review of published information available about competing products and the predicate device.

Description	Varian VariSource Remote High Dose Rate Afterloader (Predicate Device)	VariSource 200
510(k) Number	K945383	
Intended Use	High Dose Rate Brachytherapy	High Dose Rate Brachytherapy
Safe	Tungsten Alloy	Tungsten Alloy
(Maximum source strength)	370GBq	407GBq. Safe and Unit tested to meet Surface Dose Requirement
Maximum Surface Dose (IEC 601-2-17: 1µGy/h @ 1m)	<0.5 µGy/h @ 1m	<0.5 µGy/h @ 1m
Radiation Detector	Installed in room Built into unit - and connected to system interlocks	Installed in room Built into unit - and connected to system interlocks
Dimension Length Width Height	 635mm 533 mm 1097 mm	 610 mm 560 mm 1070 mm
Weight	148Kg	142 kg
Power Requirements	110/220 V +/- 10%	110/220 V +/- 10%
Power Consumption	550 VA, peak	550 VA, peak
UPS	Yes	Yes
Ambient Temperature	15 - 35°C	15 - 35°C
Relative Humidity	30% - 75%	30% - 75%
Atmospheric Pressure	70kPa - 110kPa	70kPa - 110kPa
Rotation of head	No (rotate unit)	No (rotate unit)
Variable Height head	No	No
Number of patient connection Channels	20	20
Channel Indexer Locking Mechanism	Mechanical	Electro-Mechanical
Method of Correct Catheter connection Detection	LED – Photo Transistor Pair	LED – Photo Transistor Pair
Treatment Length in Catheter	70 cm to 150cm	70 cm to 150cm
Authorized Access: Key Switch Password	 Yes Yes Yes - 3 levels	 Yes Yes Yes - 3 levels
Power Fail	UPS takes over - operator can choose to continue or interrupt treatment. An interrupted treatment may be completed at operator option at any time. UPS will power unit safely for 30 minutes - new patient treatment may not be initiated during power fail	UPS takes over - operator can choose to continue or interrupt treatment. An interrupted treatment may be completed at operator option at any time. UPS will power unit safely for 30 minutes - new patient treatment may not be initiated during power fail

HDR Product Comparison Chart

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Description	Varian VariSource Remote High Dose Rate Afterloader (Predicate Device)	VariSource 200
Emergency Source Retraction:		
Battery Back-up	Yes	Yes
Battery test prior to source extension	Yes	Yes
DC Motor	Yes	Yes
Separate Motor	Yes	Yes
Manual Crank	Yes	Yes
Manual Crank Access	On side of unit	On side of unit
Crank method	Handle on wheel	Handle on wheel
Source:		
Source Wire No	SL 777V	VS2000
Source Capsule Length	11mm	6 mm
Source Active Length	10mm	5 mm
Source Diameter	0.59mm	0.59 mm
Source Material	Iridium	Enriched Iridium
Source Wire	Solid Nickel-Titanium Alloy	Solid Nickel-Titanium Alloy
Turning Radius	17 mm in 4.7 Fr thick wall catheter, at 120 cm from turret	17 mm in 4.7 Fr thick wall catheter, at 120 cm from turret
Source Mechanical Life	Interlocked at 500 extensions	Interlocked at 1000 extensions
QA Tool		
Source Position Verification. Video image via frame grabber with plain paper print out.	Yes – External, allows daily QA of source positioning accuracy, including dummy positioning - recorded on a single sheet of paper.	Yes – Internal, allows daily QA of source positioning accuracy, including dummy positioning - recorded on a single sheet of paper.
User Interface		
Graphical User interface Operating System	DOS	DOS
Prescription Record Transfer	Floppy disk	Floppy disk
Standard Plans	On floppy disk	On floppy disk
Prescription & Reports	Printed on Paper	Printed on Paper
PC Hardware*	Intel 486 50MHz, IBM Compatible	Intel 486 50MHz, IBM Compatible
Monitor*	15" CRT	15" CRT
Printer*	Laser Printer	Laser Printer
Independent Treatment Control Panel	Yes	Yes
Regulations:		
IEC 601-2-17	Yes	Yes

*Minimum Specification

Department	*VBT Project Manager*	Date:	16th December 2005
Name	Chris Heath	Signature:	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 25 2006

Ms. Vy Tran
Director, Corporate Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way M/S E-110
PALO ALTO CA 94304-1129

Re: K061582
Trade/Device Name: VariSource 200 HDR Brachytherapy Afterloader
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: June 2, 2006
Received: June 7, 2006

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K061582
Device Name: VariSource 200 HDR Brachytherapy Afterloader

Indications For Use:

The VariSource 200 System is a High Dose Rate Brachytherapy Afterloader used to treat lesions, tumors and conditions in the body where radiation is indicated.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061582

Prescription Use ✓
(Per 21 CFR 801.109)